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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,812	07/17/2003	Joachim Buenger	MERCK 2206 P1	8982

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EXAMINER	
LAMM, MARINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,812	BUENGER ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1,4,7-9,12 and 15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,6,10,11,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/744,945.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, Claims 2, 3, 5, 6, 10, 11, 13 and 14 in the reply filed on 1/9/06 is acknowledged. The traversal is on the ground(s) that "the PTO has not established that it would pose an undue burden to examine the full scope of the application". This is not found persuasive because the search required for Group II is not required for Group I since the claimed methods are intended for different patient populations, i.e. the method of Group I is used for treating patients having skin **with** high surfactant concentration, while the method of Group II is used for protecting the skin of patients **from** high surfactant concentration.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 1, 4, 7-9, 12 and 15-17 have been withdrawn from further consideration as directed to non-elected invention.

Information Disclosure Statement

3. The information disclosure statement filed 2/6/06 fails to comply with **37 CFR 1.98(a)(2)(i), (iii) and (b)(3)**, which require the following: a legible copy of each foreign patent; for each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date. It has been placed in the

application file, but the information has been considered only to the extend it complies with 37 CFR 1.98.

Specification

4. The disclosure is objected to because of the following informalities: there is no brief description of drawings.

Appropriate correction is required.

Priority

5. The effective filing date of the instant claims is deemed to be the filing date of the instant application (**7/17/03**), as the previous priority applications SN 09/744,945 and PCT/EP99/05239 do not support the claimed limitations of the instant application, encompassing a method of protecting the skin of a human patient from exogenous high surfactant concentration comprising administering to a patient whose skin is in need of such protection a composition comprising ectoin, wherein the composition does not contain a surfactant and wherein said exogenous surfactant is not sodium dodecyl sulfate. If the Applicant disagrees, the Applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph.

Double Patenting

Duplicate Claims

6. Applicant is advised that should claims 2, 5, 10 and 13 be found allowable, claims 3, 6, 11 and 14 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Nonstatutory Obviousness-Type Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 2, 3, 5, 6, 10, 11, 13 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S.

Patent No. 6,060,071 ('071) in view of either Geria (US 4,992,476) or Idson ("Dry Skin Moisturizing and Emolliency", Cosmetics & Toiletries, Vol. 107, July 1992, 69-78), supplied by the Applicant.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). The instant claims are directed to a method of protecting the skin of a human patient from exogenous high surfactant concentration comprising administering to a patient whose skin is in need of such protection a composition comprising ectoin, wherein the composition does not contain a surfactant and wherein said exogenous surfactant is not sodium dodecyl sulfate. Claim 1 of '071 is directed to a method of treating a patient suffering from aged, dry or irritated skin or of dry, flaky scalp, comprising administering to said patient an effective amount of at least one ectoin together with a cosmetically acceptable carrier. Claim 2 of '071 is directed to a method of increasing or stabilizing the moisture content of a patient's skin, comprising administering to said patient an effective amount of at least one ectoin together with a cosmetically acceptable carrier. The claims of '071 do not recite the claimed "protecting the skin of a human patient from exogenous high surfactant concentration". However,

Geria teaches that prolonged detergent use causes dry skin. See col. 1, lines 34-41. Further, Geria teaches that the "optimum treatment for dry skin is to raise the stratum corneum's moisture level and to reestablish its integrity." See col. 1, lines 42-46. Similarly, Idson teaches that "a chief cause of skin dryness is loss of water from the surface of the skin". See p. 69. "On a practical level, dry skin is often due to defatting and dehydration of skin by alkaline detergents or solvents, which leads to chapping." See p. 70. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the method of '071 such that to use it for protecting the skin from exogenous surfactants/detergents. One having ordinary skill in the art would have been motivated to do this because dry skin is caused by dehydration due to the detergent (surfactant) use as suggested by either Geria or Idson.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2, 3, 5, 6, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the publication "RonaCare™ Ectoin The Cell Protection Factor", dated 8/2000 (thereafter "the RonaCare™ publication"), supplied by the Applicant.

The RonaCare™ publication teaches that ectoin protects the human skin cell membranes against environmental damage such as various tensides (surface active agents or surfactants, e.g. sodium lauryl sulphate, cocamidopropyl bethane, alkyl polyglucoside and sodium laureth sulphate) in concentrations that would normally cause damage. See pp. 20, 21. "Pretreatment with RonaCare™ Ectoin can substantially reduce damage to the cell membranes e.g. by tensides." See p. 22.

Thus, the RonaCare™ publication teaches each and every limitation of Claims 2, 3, 5, 6, 10, 11, 13 and 14.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 2, 3, 5, 6, 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motitschke et al. (US 6,060,071), of record, in view of either Geria (US 4,992,476) or Idson ("Dry Skin Moisturizing and Emolliency", Cosmetics & Toiletries, Vol. 107, July 1992, 69-78).

Motitschke et al. teach treating aged, dry or irritated skin comprising administering to a patient in need of such treatment an effective amount of at least one ectoin together with a cosmetically acceptable carrier. See Claim 1. Motitschke et al. also teach to a method of increasing or stabilizing the moisture content of a patient's

skin, comprising administering to said patient an effective amount of at least one ectoin together with a cosmetically acceptable carrier. See Claim 2; col. 7, lines 8-19. Further, Motitschke et al. teach that under normal conditions, the skin itself is capable of regulating its moisture content, but the skin is highly sensitive to chemical and physical factors. See col. 1, lines 15-30. Dry skin condition "can be prevented as well as counteracted by using suitable moisturizing preparations". See col. 1, lines 28-30. The compositions recited in Claim 1 and 2 of Motitschke et al. do not contain any surfactants. Motitschke et al. do not explicitly teach the claimed "protecting the skin of a human patient from exogenous high surfactant concentration". However, Geria teaches that prolonged detergent is one of the causes of dry skin. See col. 1, lines 34-41. Further, Geria teaches that the "optimum treatment for dry skin is to raise the stratum corneum's moisture level and to reestablish its integrity." See col. 1, lines 42-46. Similarly, Idson teaches that "a chief cause of skin dryness is loss of water from the surface of the skin". See p. 69. "On a practical level, dry skin is often due to defatting and dehydration of skin by alkaline detergents or solvents, which leads to chapping." See p. 70. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the method of '071 such that to use it for protecting the skin from exogenous surfactants/detergents. One having ordinary skill in the art would have been motivated to do this because dry skin is caused by dehydration due to the detergent (surfactant) use as suggested by either

Geria or Idson and the compositions of Motitschke et al. are capable of restoring the moisture level of the skin and treating or preventing skin dryness.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,964,954.

14. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
4/3/06

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER